



5.3: Predictive cell culture systems

*13 – 17 February 2012
Institute of Environmental Toxicology
Medical Faculty, University of Halle Wittenberg
Halle/Saale, Germany*

*Home Assignment (Case Studies and Course questions)
To be completed by the 30th March 2012*

Predictive cell culture systems Course:

Key questions to be tackled by the course

- ⌚ Limits and strengths of permanent versus primary cells
- ⌚ Test batteries for cytotoxicity and cellular dysfunction
- ⌚ Robust parameters to monitor cell functions
- ⌚ Use of 'omics technologies to identify critical pathways of toxicity
- ⌚ Requirements on cell culture systems for screening /high throughput techniques
- ⌚ Alternative methods and regulatory requirements

Introduction

Cell culture systems are integral part of in vitro test batteries in research and development of pharmaceuticals. They are needed to specifically assess putative activities of compounds regarding targets and to discover lead compounds as well. Predictive cell culture based in vitro tools need to cover major toxicity pathways for preclinical evaluation. They may have the power to generate robust data in screening assays on a sound cost effect relationship.

This module aims to introduce the principles of cell culture systems as a tool to monitor cellular homeostasis and early onset of functional imbalance leading to toxicity as well as their use and impact for drug development. The course will discuss strengths and limits of culture systems as experimental tools and will give insight into the overall strategy of preclinical safety evaluation. The need to establish /adapt biomarker assays will be discussed. 'New wave' biomarkers may help to improve predictivity regarding species differences and extrapolation to man.

Why join the course?

- Intense and broad training with leading experts in their field
- Balance of academic, industry and regulatory teachers provides knowledge directly applicable to drug safety assessment
- Learn cutting edge technologies as well as translational aspects of cell culture systems

Course Objectives

This course consists of 5 days in Halle with lectures and case studies followed by a week at home dedicated to individual assignments. Thus the total course will provide the participants with a comprehensive overview of predictive cell culture systems with special emphasis on application of in vitro models to drug discovery and development.

Key areas covered by this course

- Limits and strengths of permanent versus primary cells
- Robust parameters to monitor cell functions
- Early cellular responses to stressors
- Test batteries for cytotoxicity and cellular dysfunction
- Competence to cope with oxidative/cellular stress
- Pathways of toxicity involving impairment of glutathione
- Use of 'omics technologies to identify critical pathways of toxicity
- Cell cultures systems to detect substrates/inductors of cytochrome P 450/drug metabolizing enzymes
- Search for drug targets versus drug safety using in vitro tests
- Requirements on cell culture systems for screening /high throughput techniques
- Alternative methods and regulatory requirements

Target Group

The SafeSciMET programme is targeted to students, academics and professionals in the pharmaceutical industry and regulatory authorities who need a broad comprehensive understanding of the drug development process with particular emphasis on safety.

Learning outcomes

With the knowledge of this module participants should understand the concept of preclinical safety testing and the role of cell culture systems within this strategy. They should be able to interpret the basic pathways for toxicity in a broader context.

More specifically, participants will be able to:

- Be able to interpret strengths and limits of specific cell culture systems
- Be able to discriminate between target directed assays, in vitro and in vivo test for safety
- Be able to extrapolate findings from in vitro test batteries to develop criteria to pre-select compounds
- Be aware of the new technologies (Omics; use of stem cells, disease models) to assess safety of pharmaceuticals
- Get insight into the network of experimental concepts in preclinical safety before first application
- Know and understand the lessons learned from historical cases of drug toxicity
- Be aware about semantics of key phrases in communication of anticipated effects/risks in pharmaceutical R&D as well as social groups



Course Programme

The Syllabus

A syllabus containing an introductory chapter, lecture hand outs, list of abbreviations, definitions and reading materials will be provided by the course leader 14 days prior to the course. The material for the home assignment will be provided during the first week of the course.

Assessment

The assessment is based on a 2-hour written examination on the last day of the course and on the evaluation of the home assessment

Type	The purpose of the examination is to test that the examinee has a broad knowledge and comprehension of the drug development process as a whole. The percentage of items on the test devoted to a particular topic will roughly correspond to the emphasis given the topic in teaching of the course: Experimental Design/Biostatistics: 30% Pre-clinical : 50% Clinical : 5% Translational : 15%
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Assessors(s)	Course Directors
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Exam aids	All written exam aids are allowed.
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Course administrator:	Heidi Foth, Professor of Environmental Toxicology, Medical Faculty, Martin-Luther-University of Halle-Wittenberg Franzosenweg 1a D-06112 Halle/Saale, Germany Phone: +49-3455571630 (Secretary) Heidi.foth@medizin.uni-halle.de
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Practical Information

Course Credits:	3 ECTS credits
Level:	Master's level (second cycle higher education)
Course Dates:	13 – 17 February 2012
Location:	Institute of Environmental Toxicology, Medical Faculty, Martin-Luther-University of Halle-Wittenberg Franzosenweg 1a D-06112 Halle/Saale, Germany
Teaching methods:	Lectures, case workgroup discussions, presentations and discussions. In order to emphasize the flow of the process, the course is to a large extent based on the use of cases in both lectures and assignments.
Student Workload:	Preparation: 12 hours Course: 38 hours Assignment: 38 Examination: 2 hours Total: 90
Course Fee:	2,500 Euro—750 Euro (dependant on category of student) (please visit www.SafeSciMET.eu . How to apply for more information)
Application deadline:	Deadline 13. January 2012
Course Capacity:	Number of participants 20
Language:	The official language of the course is English. No simultaneous translations will be provided
Course notes:	Notes (literature) used in the course Marquardt et al, Toxicology, Academic Press 1999 S. Gad, Drug Safety Evaluation, Wiley 2002 Alberts et al, Molecular Biology of the Cell, 200x, Garland-Publishing Lewin, Genes, 200x, Prentice Hall
Course accreditation:	The course meets the criteria for continuous professional Development (CPD) diplomas, and it will be part of a (forthcoming European) Masters of advanced Safety Sciences degree. More information can be obtained through our website: http://www.SafeSciMET.eu

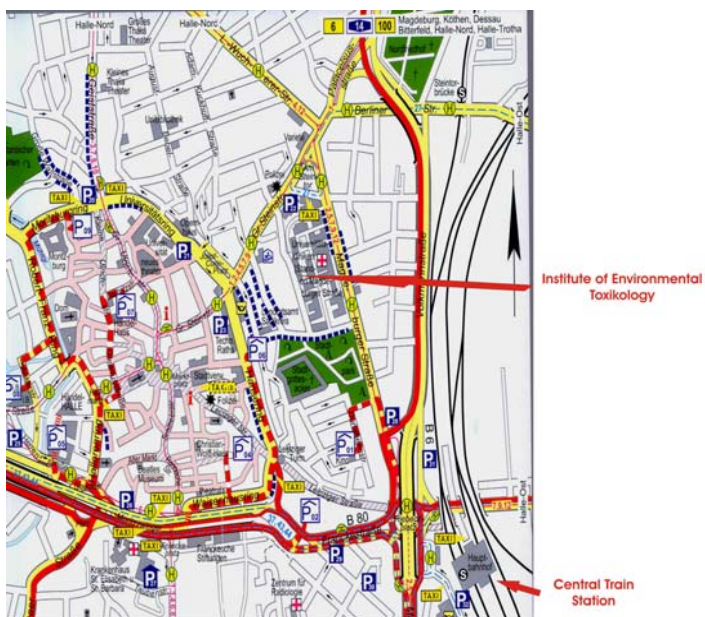
Course Leaders

Prof. Heidi Foth, Professor of Environmental Toxicology, Medical Faculty, Martin-Luther-University of Halle-Wittenberg
Franzosenweg 1a, D-06112 Halle/Saale, Germany

PD Dr. Stefan O. Mueller, Merck KGaA - Merck Serono R&D - NCD/Toxicology
Postcode U009/101, Frankfurter Str. 250, 64293 Darmstadt - Germany

Lecturers

Heidi Foth	University of Halle, DE
Stefan O Mueller	Merck KGaA - Merck Serono R&D, DE
Phil Hewitt	Merck KGaA - Merck Serono R&D, DE
Thomas Broschard	Merck KGaA - Merck Serono R&D, DE
Marcel Leist	University of Konstanz, DE
Manfred Liebsch	BFR, Berlin, DE
Bettina Grasl-Knaup	University of Vienna, AUS
Jan Hengstler	IfaDo, DE
Marc Pallardy	University Paris-Sud, FR



REGISTRATION

Please visit www.safescimet.eu to register. On the homepage, please go to **How to Apply** and sign up:

[For MSc of Advanced Safety Courses](#)

[For Continuing Professional Development \(CPD\)](#)

[For Single courses](#)

You will be notified that your registration has been received

The closing date to register for this course is 13 January 2012

Please note that the number of participants is limited to 20. It is highly advisable to send in your registration form as soon as possible. Registration will be made on a **first come first served** basis

TRANSPORT

The course takes place in Halle/Saale, Germany, 0.5 km from the central train station (see map), approx. 30 minutes by train from Leipzig-Halle Airport.

ACCOMMODATION

Hotels can be arranged individually via www.stadtmarketing-halle.de/.

CANCELLATION

January 2012. Before that date the Course fee will be refunded except for an administrative fee of EUR 75,- After that date, no refunds can be made for cancellations